



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

SL

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/815,504 | 03/23/2001 | Michael Castro | 2658 | 5642 |

530 7590 05/20/2004

LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK
600 SOUTH AVENUE WEST
WESTFIELD, NJ 07090

| |
|----------|
| EXAMINER |
|----------|

STEWART, ALVIN J

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

3738

DATE MAILED: 05/20/2004

26

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/815,504

Applicant(s)

CASTRO ET AL.

Examiner

Alvin J Stewart

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/15/04 has been entered.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the Applicants' representative has not disclose in the specification an endless groove and an inner surface which extends perpendicularly to the longitudinal axis of the implant.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the inner surface which extends perpendicularly to the longitudinal axis of the implant member must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21-29, 35, 36 and 41-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Schönhöffer US Patent 5,571,192.

Schönhöffer discloses a fusion implant comprising an implant member (2), the implant member (2) has a first end, a second end, and an outer wall (3) defining an internal cavity (see fig. 3). The outer wall has a plurality of grooves (the valleys of the threaded surface have been interpreted as the plurality of the grooves), which encircle the whole circumference of the outer wall, and segments the implant member into a plurality of ring-like segments. Each ring-like segment includes a plurality of apertures (9 & 10) extending in communication with the internal cavity. The first and second ends of the implant member are in mechanical connection to a plurality of caps (1 & 1').

Regarding claim 23, the grooves are capable of acting as a cutting guide. For example, the outer thread of the tubular member (2) of the Schönhöffer is capable of creating a threaded bore into the walls of the vertebrae.

Regarding claim 24, the grooves are capable of acting as a measurement guide. For example, by measuring the separation between one groove and the collar (6) and/or the thickened center region (8) the surgeon is capable of determining an exact length.

Regarding claim 26, see the notes made by the Examiner in the attachment determining the different lengths in the segments.

Regarding claim 27, see Figure 2.

Regarding claim 29, the end cap has a face (15) having at least one aperture (see Figure 11).

Regarding claim 36, the Examiner interpreted the plurality of locking pins as the plurality of peaks created by the threaded bore in each cap (see Fig. 1).

Regarding claim 41, the prior art discloses an implant that can be set in any vertebra disk space at any acceptable length range. The length of the implant is increased by rotating the center element (2) in order to force out the end elements and bring their outer ends at a certain length. The length, of course, will depend on the natural length of the natural disk that is going to be replaced. Therefore, the Examiner has interpreted lines 14-16 broadly. If the surgeon knows the total length of the ablated natural disk and the initial length of the artificial implant then the surgeon by looking at the grooves is capable of determining (before implantation) the desire length of the implant when the center element is rotated. Therefore, the surgeon can measure the length of the disk space by placing physically the implant in the expanded state before is implanted.

Note: The claims disclosed above are given their broadest reasonable interpretation, especially claim 41, lines 14-16. In re Pearson, 181 USPQ 641 (CCPA 1974).

Art Unit: 3738

Regarding claim 42, see col. 2, lines 9-12.

Claims 21-30, 35, 36 and 41-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Michelson US Patent 6,558,423 B1.

Michelson discloses a fusion implant comprising an implant member (100), the implant member has a first end, a second end (see attachment), and an outer wall defining an internal cavity (see figs. 50-53). The outer wall has a plurality of grooves (see attachment), which encircle the whole circumference of the outer wall, and segments the implant member into a plurality of ring-like segments (see attachment). Each ring-like segment includes a plurality of apertures (see attachment) extending in communication with the internal cavity. The second end of the implant member is in mechanical connection to a cap (112).

Regarding claim 23, the grooves are capable of acting as a cutting guide.

Regarding claim 24, the grooves are capable of acting as a measurement guide. For example, by measuring the separation between one groove and the collar and/or the thickened center region the surgeon is capable of determining an exact length.

Regarding claim 26, see the notes made by the Examiner in the attachment determining the different lengths in the segments.

Regarding claim 27, see Figure 2.

Regarding claim 29, the end cap has a face having at least one aperture (see Figure 3).

Regarding claim 36, the Examiner interpreted the plurality of locking pins as the plurality of peaks created by the threaded bore in each cap.

Regarding claim 41, the prior art discloses an implant that can be set in any vertebra disk space at any acceptable length range. The length, of course, will depend on the natural length of

Art Unit: 3738

the natural disk that is going to be replaced. If the surgeon knows the total length of the ablated natural disk and the initial length of the artificial implant then the surgeon by looking at the grooves is capable of determining (before implantation) the desired length of the implant when the center element is rotated. Therefore, the surgeon can measure the length of the disk space by placing physically the implant in the expanded state before it is implanted.

The claims disclosed above are given their broadest reasonable interpretation. In re Pearson, 181 USPQ 641 (CCPA 1974).

Regarding new limitations in claims 44 and 47-52, see attachment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schönhöffer US Patent 5,571,192 in view of Schönhöffer US Patent 6,015,436.

Schönhöffer ('192) discloses the invention substantially as claimed. However, Schönhöffer does not disclose a plurality of spikes arranged radially about the face of the end caps.

Schönhöffer teaches an implantable disk prosthesis comprising an implant member (1) having a first end and a second end having a plurality of spikes (12) radially (see Figure 3) about the face of the first and second ends for the purpose of having a good attachment with the walls of the vertebrae (see col. 4, lines 13-24).

Art Unit: 3738

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the distal ends of the Schönhöffer reference ('192) with the distal ends spikes of the Schönhöffer reference ('436) in order to have a good attachment with the walls of the vertebrae.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J Stewart whose telephone number is 703-305-0277. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. Stewart

Alvin Stewart
May 14, 2004.

ATTACHMENT

U.S. Patent

May 6, 2003

Sheet 1 of 22

US 6,558,423 B1

